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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,857	11/20/2001	Roberto Macina	DEX-0273	1527

26259 7590 10/02/2003

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EXAMINER	
WILDER, CYNTHIA B	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,857	MACINA ET AL.	
	Examin r	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 7-9 and 15, drawn to an isolated nucleic acid, classified in class 536, subclass 23.1.

II. Claims 6 and 14, drawn to a hybridization method for determining the presence of lung specific nucleic acid (LSNA), classified in class 435, subclass 6.

III. Claims 10, 11, 15 drawn to an isolated polypeptide, classified in class 530, subclass 350.

IV. Claim 12, drawn to an antibody, classified in class 424, subclass 130.1.

V. Claims ~~12~~ 13, 14, drawn to a protein binding assay for determining the presence of lung specific nucleic acid, classified in class 435, subclass 7.1.

VI. Claim 16, drawn to a method of treating a patient with drug, classified in class 514, subclass 12.

VII. Claim 17, drawn to a vaccine, classified in class 424, subclass 184.1.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct SEQ ID Numbers. Each sequence is patentably distinct because the sequences are structurally unrelated sequences, and a further restriction is applied to each Group. Applicant must further elect a single SEQ ID NO. Applicant must specifically identify each of the corresponding SEQ ID NO: X, SEQ ID NO: Y for the sequence elected along with the corresponding elected claims.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. The sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence or amino acid sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 eq seq. By statute, "[i}f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the invention". "35 U.S.C. 121." Pursuant to this statute, the rules provided that "[i]f two or more independent and distinct invention are claimed in a single application, the examiner in his action shall require the Applicant....to elect that invention to which his claim shall be restricted". 37 CFR 1.142(a). See also 37 CFR 1.141(a).

Applicant is advised that examination will be restricted to only the elected SEQ ID NO. and should not to be construed as a species election. Non-elected sequences in multiple sequence claims will be withdrawn from prosecution.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I, III, IV and VII are unrelated products. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are structurally and functionally distinct. For example, invention I is drawn to an isolated nucleic acid which is composed of nucleotides and functions in methods of nucleic acid hybridization and amplification whereas invention III is drawn to an isolated polypeptide which is composed of amino acids linked by peptide bonds and arrange in complex combinations of alpha helices, beta pleated sheets, hydrophobic and hydrophilic domains. The polypeptide can function as fusion proteins with enzymatic functions or in ligand/receptor binding assays. Invention IV differs from the other inventions in that invention IV is drawn to an antibody which is composed of amino acids linked by peptide bonds. Antibodies are glycosylated and their tertiary structure are unique, where four subunits

associated via disulfide bonds form into a Y-shaped symmetric dimer. The antibodies can function in immunoassays and finally invention VII which is drawn to a vaccine is distinct from the other inventions in that the vaccine comprises a preparation of killed microorganisms, living attenuated organisms or living fully virulent organisms that is administered to produce or artificially increase immunity to a particular disease. The different inventions are patentably distinct requiring different fields of search which would require an undue burden to the examiner if not restricted.

2. Inventions I and II, VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product comprising the isolated polynucleotide of invention I can be used in a matcrially different process besides that of inventions II and IV. The isolated polynucleotide of invention I can be used in methods of amplification to determine a variant sequence of interest or in nucleic acid cloning or purification assay or alternatively, the isolated polynucleotide can be used in antisense or aptamer studies.

3. Inventions III, IV and V, VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide of invention III and the antibody of invention IV can be used in a materially different process besides in the methods of invention V and VI.

The antibody and polypeptide can be used in methods of mutagenesis or in two-hybrid system or in receptor/ligand binding studies or immunoassays.

4. Inventions II, V, VI are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation resulting in different effects. For example, the method of invention II is drawn to a hybridization method to determine the presence of LSNA in a sample whereas the method of invention V is drawn to ligand (protein) binding assay or solid phase assay for determining the presence of LSNA in a sample whereas the method of invention VI is drawn to a method of treating a patient or cell from patient with molecule or drug which stimulates a response. The different inventions are patentably distinct requiring different fields of search which would require an undue burden on the examiner if not restricted.

5. Because these inventions are distinct for the reasons given above and the search required for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and on Friday from 9:30 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0196.

CYNTHIA WILDER
PATENT EXAMINER

Cynthia B. Wilder, Ph.D.
Examiner
Art Unit 1637

cbw
September 29, 2003

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September 29, 2003